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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/059,635 | 01/29/2002 | Shifeng Bill Wei | ORT-1585 | 7718 |

27777 7590 03/17/2003
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EXAMINER

OH, SIMON J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1615

DATE MAILED: 03/17/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/059,635

Applicant(s)

WEI ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicants' amendment and response, received 09 December 2002.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 depends on Claim 1, which has been cancelled with the applicants' amendment of 09 December 2002. Claims 28-30 are rejected for depending upon Claim 22.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 20, 31, 32, and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Hogan *et al.*

The Hogan *et al.* document teaches a substrate coating for the electrostatic deposition of active substances (See Page 1, Lines 4-18; Page 3, Lines 3-27; and Page 5, Line 33 to Page 6, Line 11). This material, in its powder form, has a particle size of less than 50 microns (See Page 8, Lines 7-16); and in one preferred embodiment, the powdered material has a mean particle size of about 10 microns, and substantially no particles larger than 100 microns in diameter (See Page 9, Lines 29-31). Polyethylene glycol with molecular weights of 20,000 and 6,000 are used in the coating material (See Example 1, Page 31, Lines 12-13; and Example 6, Page 34, Line 26). Various types of active agents may be included in the powder coating material, including oral contraceptive agents (See Page 19, Line 17). Preferably, the coating material comprises at least 0.5% by weight of the active agent based on the weight of the powder coating material. An example is cited where a 10 mg coating on a tablet may contain approximately at least 0.05 mg of the active ingredient (See Page 19, Line 35 to Page 20, Line 3).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 20-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan *et al.*

The relevant portions of Hogan *et al.* are detailed in the above rejection of Claims 20, 31, 32, and 34-36 under 35 U.S.C. 102(b).

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Hogan *et al.* does not explicitly mention norgestimate or ethinyl estradiol as suitable active agents for use in the disclosed powder coating. However, it would be obvious to one of ordinary skill in the art that the term "oral contraceptive agents" encompasses norgestimate or ethinyl estradiol, and that one of ordinary skill would know appropriate dosage amounts for these drugs. Claim limitations drawn to specific amounts of the active ingredients are also made obvious by the disclosure of Hogan on Page 19, Line 35 to Page 20, Line 3. Claim limitations drawn to particle sizes of the active ingredients are made obvious by the disclosure on Page 9, Lines 29-31, regarding the particle size of the powder coating, which, in one possible embodiment, would presumably comprise both polyethylene glycol as well as the active ingredient.

Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 09 December 2002 have been fully considered but they are not persuasive.

Based on the applicant's response, the primary basis for claiming patentability is directed towards the claim limitation regarding the triboelectrically charged medicament bearing a negative charge. However, the language of Claim 20, particularly with the use of the word "when" in the third line of the claim, renders this limitation as an optional one, and therefore, not critical to the instantly claimed invention. As the applicant has not provided a showing of criticality of this particular claim limitation, the above prior art rejections are deemed proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjo
March 13, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600